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Application No. 10/616,218 Amendment and Election

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Customer No. 01933

Listing of Claims:

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 (Original) Apparatus for treating a fracture of a bone of a subject, comprising:

an intramedullary (IM) nail, adapted to be inserted in a medullary canal of the bone of the subject, and comprising a proximal head that defines at least one hole therethrough; and a sleeve, comprising a locking mechanism, which locking mechanism is adapted to engage the hole when the sleeve is inserted in the hole, such engagement preventing rotational and longitudinal movement between the sleeve and the hole.

- 2. (Original) Apparatus according to claim 1, comprising a screw, wherein the sleeve is adapted to slidably receive the screw.
- 3. (Original) Apparatus according to claim 1, wherein the proximal head is shaped so as to define a female coupling element located on a surface of the hole, and wherein the locking mechanism comprises a depressible male coupling element, configured to engage the female coupling element so as to prevent the rotational and longitudinal movement.

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- 4. (Original) Apparatus according to claim 3, wherein the female coupling element is shaped to define a notch.
- 5. (Original) Apparatus according to claim 3, wherein the male coupling element comprises a tab.
- 6. (Original) Apparatus according to claim 3, wherein the depressible male coupling element is adapted to engage the female coupling element when the sleeve is inserted in the hole to a fixed depth and then rotated until the depressible male coupling element engages the female coupling element.
- 7. (Original) Apparatus for treating a fracture of a bone of a subject, comprising an intramedullary (IM) nail, adapted to be inserted in a medullary canal of the bone of the subject, the IM nail comprising a proximal head having a distal portion and a proximal portion, the distal portion having a distal diameter, and the proximal portion having a proximal diameter less than or equal to about 80% of the distal diameter.
- 8. (Original) Apparatus according to claim 7, wherein the proximal diameter is less than or equal to about 50% of the distal diameter.

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- 9. (Original) Apparatus according to claim 7, wherein the proximal diameter is equal to between about 5 mm and about 10 mm and the distal diameter is equal to between about 11 mm and about 17 mm.
- 10. (Original) Apparatus according to claim 7, wherein a length of the proximal portion is equal to between about 10% and about 50% of a length of the distal portion.
- 11. (Original) Apparatus according to claim 7, wherein the distal portion defines at least one hole therethrough, and comprising a sleeve, which comprises a locking mechanism, which locking mechanism is adapted to engage the hole when the sleeve is inserted in the hole, such engagement preventing rotational and longitudinal movement between the sleeve and the hole.
- 12. (Original) Apparatus for treating a fracture of a bone of a subject, comprising:

an intramedullary (IM) nail, adapted to be implanted in the bone, such that no portion of the IM nail extends to an external surface of the bone.

13. (Original) Apparatus according to claim 12, wherein the IM nail comprises a proximal head that defines one or more

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proximal head holes therethrough, and comprising a locating device, which comprises:

- one or more connecting elements, fixed to a distal end of the locating device, the connecting elements adapted to be temporarily coupled to respective ones of the proximal head holes; and
- a location indicating element, fixed to a proximal end of
 the locating device, the location indicating element adapted to
 indicate, when the connecting elements are coupled to the holes,
 a location on the external surface of the bone substantially
 directly over a location of a proximal end of the proximal head.
 - 14. (Original) Apparatus according to claim 13, wherein the one or more connecting elements comprise exactly one connecting element.
 - 15. (Original) Apparatus according to claim 13, wherein each of the one or more connecting elements comprises a locking mechanism, adapted to engage one of the proximal head holes when the connecting element is inserted in the proximal head hole, such engagement preventing rotational and longitudinal movement between the connecting element and the proximal head hole.

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16. (Original) Apparatus according to claim 13, comprising one or more sleeves, adapted to be coupled to respective ones of the proximal head holes,

wherein the one or more connecting elements are adapted to be coupled to the respective ones of the proximal head holes by being coupled to respective ones of the sleeves when the one or more sleeves are coupled to the respective ones of the proximal head holes.

- 17. (Original) Apparatus according to claim 16, wherein each of the one or more sleeves comprises a locking mechanism, adapted to engage one of the holes when the sleeve is inserted in the hole, such engagement preventing rotational and longitudinal movement between the sleeve and the hole.
- 18. (Original) Apparatus according to claim 12, wherein the IM nail comprises a proximal head having a proximal end, the proximal head defining at least one hole therethrough, and defining a longitudinal channel, open to the hole and to the proximal end, and

comprising a bendable, resilient elongated element, which comprises a sharp tip, the element adapted to be inserted (a) into the hole, (b) through at least a portion of the channel, (c) through the proximal end of the proximal portion, and (d) through

- the bone, so as to indicate a location on the external surface of the bone substantially directly over the proximal end of the proximal head.
 - 19. (Original) Apparatus according to claim 18, wherein the tip comprises a screw thread.
 - 20. (Original) Apparatus according to claim 18, wherein the tip comprises a drill bit.
 - 21. (Original) Apparatus for locating an intramedullary (IM) nail implanted in a bone of subject, the IM nail having a proximal head that defines one or more holes therethrough, the apparatus comprising:
- one or more connecting elements, adapted to be disposed at a distal end of the apparatus, the connecting elements adapted to be temporarily coupled to respective ones of the holes; and a location indicating element, fixed to a proximal end of the apparatus, the location indicating element adapted to indicate, when the connecting elements are coupled to the holes, a location on an external surface of the bone substantially directly over a location of a proximal end of the proximal head, when no portion of the IM nail extends to the external surface of the bone.

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- 22. (Original) Apparatus according to claim 21, wherein the one or more connecting elements comprise exactly one connecting element.
- 23. (Original) Apparatus according to claim 21, wherein each of the one or more connecting elements comprises a locking mechanism, adapted to engage one of the holes when the locking mechanism is inserted in the hole, such engagement preventing rotational and longitudinal movement between the connecting element and the hole.
- 24. (Original) Apparatus according to claim 21, comprising one or more sleeves, adapted to be coupled to respective ones of the holes,

wherein the one or more connecting elements are adapted to be coupled to the respective ones of the holes by being coupled to respective ones of the sleeves when the one or more sleeves are coupled to the respective ones of the holes.

- 25. (Original) Apparatus according to claim 24, wherein each of the one or more sleeves comprises a locking mechanism, adapted to engage one of the holes when the sleeve is inserted in the hole, such engagement preventing rotational and longitudinal movement between the sleeve and the hole.
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- 26. (Original) Apparatus for treating a fracture of a bone of a subject, comprising an intramedullary (IM) nail, adapted to be inserted in a medullary canal of the bone of the subject, the IM nail comprising a proximal head having a distal portion and a proximal portion, the proximal portion visually discrete from the distal portion, the proximal portion adapted to aid in locating the IM nail, and the distal portion adapted to be coupled to at least one element.
- 27. (Original) Apparatus according to claim 26, wherein the distal portion is adapted to be coupled to the at least one element, the at least one element being selected from the list consisting of: a nail, a screw, a pin, and a sleeve.
- 28. (Original) Apparatus according to claim 26, wherein the distal portion defines at least one hole therethrough, and comprising a sleeve, which comprises a locking mechanism, which locking mechanism is adapted to engage the hole when the sleeve is inserted in the hole, such engagement preventing rotational and longitudinal movement between the sleeve and the hole.

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29. (Original) A method for treating a fracture of a bone of a subject, comprising:

inserting, in a medullary canal of the bone of the subject, an intramedullary (IM) nail having a proximal head that defines at least one hole therethrough;

inserting a sleeve in the hole; and

locking the sleeve to the hole by moving the sleeve within the hole, so as to prevent rotational and longitudinal movement between the sleeve and the hole.

- 30. (Original) A method according to claim 29, comprising inserting a screw through the sleeve.
- 31. (Original) A method according to claim 29, wherein the proximal head is shaped to define a female coupling element located on a surface of the hole, wherein the sleeve includes a depressible male coupling element, and wherein locking the sleeve to the hole comprises engaging the depressible male coupling element in the female coupling element so as to prevent the rotational and longitudinal movement.
- 32. (Original) A method according to claim 31, wherein the female coupling element is shaped to define a notch, and wherein

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locking the sleeve to the hole comprises engaging the depressible male coupling element in the notch.

- 33. (Original) A method according to claim 31, wherein the male coupling element includes a tab, and wherein locking the sleeve to the hole comprises engaging the tab in the female coupling element.
- 34. (Original) A method according to claim 31, wherein locking the sleeve to the hole comprises:

inserting the sleeve in the hole to a fixed depth; and rotating the sleeve until the depressible male coupling element engages the female coupling element.

- 35. (Original) A method for treating a fracture of a bone of a subject, comprising inserting, in a medullary canal of the bone of the subject, an intramedullary (IM) nail having a proximal head having a distal portion and a proximal portion, the distal portion having a distal diameter, and the proximal portion having a proximal diameter less than or equal to about 80% of the distal diameter.
- 36. (Original) A method according to claim 35, wherein inserting the IM nail comprises inserting the IM nail so that an

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end of the proximal portion is generally flush with an external surface of the bone.

- 37. (Original) A method according to claim 36, comprising determining a location of the IM nail for post-operative access to the IM nail, by determining a location of the end of the proximal portion.
- 38. (Original) A method according to claim 35, wherein inserting the IM nail comprises inserting the IM nail so that an end of the proximal portion protrudes from an external surface of the bone.
- 39. (Original) A method according to claim 38, comprising determining a location of the IM nail for post-operative access to the IM nail, by determining a location of the end of the proximal portion.
- 40. (Original) A method according to claim 35, wherein the proximal diameter is less than or equal to about 50% of the distal diameter.
- 41. (Original) A method according to claim 35, wherein the proximal diameter is equal to between about 5 mm and about 10 mm

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and the distal diameter is equal to between about 11 mm and about 17 mm.

- 42. (Original) A method according to claim 35, wherein a length of the proximal portion is equal to between about 10% and about 50% of a length of the distal portion.
- 43. (Original) A method according to claim 35, wherein the distal portion defines at least one hole therethrough, and comprising:

inserting a sleeve in the hole; and

- locking the sleeve to the hole by moving the sleeve within the hole, so as to prevent rotational and longitudinal movement between the sleeve and the hole.
- 44. (Original) A method for treating a fracture of a bone of a subject, comprising implanting an intramedullary (IM) nail in the bone, such that no portion of the IM nail extends to an external surface of the bone.
- 45. (Original) A method according to claim 44, wherein the IM nail has a proximal head that defines one or more proximal head holes therethrough, and comprising temporarily coupling one or more connecting elements to respective ones of the holes, in a

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- 5 manner that brings a location indicating element to a position from which the location indicating element indicates a location on an external surface of the bone substantially directly over a location of a proximal end of the proximal head, when no portion of the IM nail extends to the external surface of the bone.
 - 46. (Original) A method according to claim 45, wherein temporarily coupling the one or more connecting elements to respective ones of the holes comprises temporarily coupling exactly one connecting element to exactly one hole.
 - 47. (Original) A method according to claim 45, wherein temporarily coupling each of the connecting elements to a respective one of the holes comprises temporarily locking the connecting element to the hole, so as to prevent rotational and longitudinal movement between the connecting element and the hole.
 - 48. (Original) A method according to claim 45, wherein temporarily coupling each of the connecting elements to a respective one of the holes comprises coupling a sleeve to the hole, and temporarily coupling the connecting element to the sleeve.

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- 49. (Original) A method according to claim 48, wherein temporarily coupling the connecting element to the sleeve comprises temporarily locking the sleeve to the hole, so as to prevent rotational and longitudinal movement between the sleeve and the hole.
- 50. (Original) A method according to claim 44, wherein the IM nail has a proximal head that has a proximal end, the proximal head defining: (a) at least one hole therethrough, and (b) a longitudinal channel, the channel open to the hole and to the proximal end, the method comprising inserting a bendable, resilient elongated element, having a sharp tip,
 - (a) into the hole,
 - (b) through at least a portion of the longitudinal channel,
 - (c) through the proximal end of the proximal portion, and
- 10 (d) through the bone,

so as to indicate a location on an external surface of the bone substantially directly over the proximal end of the proximal head, when no portion of the IM nail extends to the external surface of the bone.

51. (Original) A method according to claim 50, wherein inserting the element comprises punching the tip through the bone.

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- 52. (Original) A method according to claim 50, wherein inserting the element comprises screwing the tip through the bone.
- 53. (Original) A method according to claim 50, wherein inserting the element comprises drilling the tip through the bone.
- 54. (Original) A method for locating an intramedullary (IM) nail implanted in a bone of subject, the IM nail having a proximal head that defines one or more holes therethrough, the method comprising temporarily coupling one or more connecting elements to respective ones of the holes, in a manner that brings a location indicating element to a position from which the location indicating element indicates a location on an external surface of the bone substantially directly over a location of a proximal end of the proximal head, when no portion of the IM nail extends to the external surface of the bone.
 - 55. (Original) A method according to claim 54, wherein temporarily coupling the one or more connecting elements to respective ones of the holes comprises temporarily coupling exactly one connecting element to exactly one hole.

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- 56. (Original) A method according to claim 54, wherein temporarily coupling each of the connecting elements to a respective one of the holes comprises temporarily locking the connecting element to the hole, so as to prevent rotational and longitudinal movement between the connecting element and the hole.
- 57. (Original) A method according to claim 54, and comprising coupling the connecting elements to the location indicating element.
- 58. (Original) A method according to claim 54, wherein temporarily coupling each of the connecting elements to a respective one of the holes comprises coupling a sleeve to the hole, and temporarily coupling the connecting element to the sleeve.
- 59. (Original) A method according to claim 58, wherein temporarily coupling the connecting element to the sleeve comprises temporarily locking the sleeve to the hole, so as to prevent rotational and longitudinal movement between the sleeve and the hole.

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- 60. (Original) A method for locating an intramedullary (IM) nail implanted in a bone of a subject, the IM nail having a proximal head that has a proximal end, the proximal head defining at least one hole therethrough, the method comprising inserting a bendable, resilient elongated element, having a sharp tip,
 - (a) into the hole,

surface of the bone.

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- (b) through at least a portion of a longitudinal channel defined by the proximal head, the channel open to the hole and to the proximal end,
 - (c) through the proximal end of the proximal portion, and
- (d) through the bone,
 so as to indicate a location on an external surface of the bone
 substantially directly over the proximal end of the proximal
 head, when no portion of the IM nail extends to the external
- 61. (Original) A method according to claim 60, wherein inserting the element comprises punching the tip through the bone.
- 62. (Original) A method according to claim 60, wherein inserting the element comprises screwing the tip through the bone.

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- 63. (Original) A method according to claim 60, wherein inserting the element comprises drilling the tip through the bone.
- 64. (Original) A method for treating a fracture of a bone of a subject, comprising:

inserting, in a medullary canal of the bone of the subject, an intramedullary (IM) nail having a proximal head having a distal portion and a proximal portion, the proximal portion visually discrete from the distal portion;

positioning the proximal portion to aid in locating the IM nail; and

coupling at least one element to the distal portion.

- 65. (Original) A method according to claim 64, wherein coupling the at least one element comprises coupling an element selected from the list consisting of: a nail, a pin, a screw, and a sleeve.
- 66. (Original) A method according to claim 64, wherein the distal portion defines at least one hole therethrough, and comprising:

inserting a sleeve in the hole; and

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- locking the sleeve to the hole by moving the sleeve within the hole, so as to prevent rotational and longitudinal movement between the sleeve and the hole.
 - 67. (Original) Apparatus for use with an intramedullary (IM) nail implanted in a bone of subject, the IM nail having a proximal portion and a distal portion that defines one or more holes therethrough, the apparatus comprising:
 - a support, adapted to be coupled to the proximal portion; a pin, adapted to be inserted through, at any given time, one of the holes and into the bone in a vicinity of a fracture of the bone; and
- a multi-axial control element, adapted to be coupled to the support and to the pin, and to move the pin translationally and rotationally, so as to reduce and align the fracture, respectively.
 - 68. (Original) Apparatus according to claim 67, wherein the multi-axial control element comprises a biaxial control element, which is adapted to move the pin in a cephalad direction and rotationally, so as to reduce and align the fracture, respectively.

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- 69. (Original) Apparatus according to claim 68, wherein the biaxial control element comprises a first member and a second member, both coupled to the support, the first and second members comprising a first set screw and a second set screw, respectively, the first and second set screws adapted to:
- move the pin in the cephalad direction when both of the first and second set screws are rotated substantially simultaneously, and

move the pin rotationally when exactly one of the first and second set screws is rotated.

- 70. (Original) Apparatus according to claim 68, wherein the biaxial control element comprises a shaped element coupled to at least one of the set screws, such that rotation of the at least one of the set screws in a first direction induces movement of the pin in the cephalad direction, and such that rotation of the at least one of the set screws in a second direction, opposite to the first direction, induces movement of the pin in the caudal direction.
- 71. (Original) Apparatus according to claim 68, wherein the holes are elongated in parallel with a longitudinal axis of the IM nail.

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72. (Original) Apparatus for treating a fracture of a bone of a subject, comprising:

an intramedullary (IM) nail, adapted to be implanted in an intramedullary canal of the bone, the IM nail comprising a proximal portion and a distal portion that defines one or more holes therethrough; and

an introducer, comprising:

- a support, adapted to be coupled to the proximal portion;
- a pin, adapted to be inserted through, at any given time, one of the holes and into the bone in a vicinity of the fracture; and
 - a multi-axial control element, adapted to be coupled to the support and to the pin, and to move the pin translationally and rotationally, so as to reduce and align the fracture, respectively.
 - 73. (Original) Apparatus according to claim 72, wherein the multi-axial control element comprises a biaxial control element, which is adapted to move the pin in a cephalad direction and rotationally, so as to reduce and align the fracture, respectively.
 - 74. (Original) Apparatus for use with an intramedullary (IM) nail implanted in a bone of subject, the IM nail having a

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proximal portion and a distal portion that defines one or more holes therethrough, the apparatus comprising:

a support, comprises means for coupling the support to the proximal portion;

a pin, adapted to be inserted through, at any given time, one of the holes and into the bone in a vicinity of a fracture of the bone; and

means for moving the pin translationally and rotationally, so as to reduce and align the fracture, respectively.

- 75. (Original) Apparatus according to claim 74, wherein the means for moving the pin comprise means for moving the pin in a cephalad direction and rotationally, so as to reduce and align the fracture, respectively.
- 76. (Original) A method for treating a fracture of a bone of a subject, the method comprising:

inserting an intramedullary (IM) nail in an intramedullary canal of the bone, the IM nail having a proximal portion and a distal portion that defines one or more holes therethrough;

inserting a pin through one of the holes and into the bone in a vicinity of the fracture;

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temporarily coupling, via at least one intermediary element, a portion of the pin external to a body of the subject to the proximal portion of the IM nail; and

moving the pin translationally and rotationally, so as to reduce and align the fracture, respectively.

- 77. (Original) A method according to claim 76, wherein moving the pin translationally comprises moving the pin in a cephalad direction.
- 78. (New) Apparatus for treating a fracture of a bone of a subject, comprising:

an intra osseal body adapted to be inserted substantially entirely inside a bone to secure a fracture of the bone, such that substantially no portion of the body extends outside an external surface of the bone; and

a retrieving device adapted to engage the body while the body is inserted in the bone, for locating the body in the bone and for enabling access to the body while the body is in the bone.

79. (New) Apparatus according to claim 78, wherein the retrieving device comprises:

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a locating device including at least one connecting element, fixed to a distal end of the locating device, the at least one connecting element being adapted to be temporarily coupled to the body; and

a location indicating element, fixed to a proximal end of the locating device, the location indicating element being adapted to indicate, when the at least one connecting element is coupled to the body, a location on an external surface of the bone substantially directly over a location of a proximal end of the body.

- 80. (New) Apparatus according to claim 79, wherein the body has a head portion having at least one head hole therein, and wherein the at least one connecting element comprises a member arranged to be received in a head hole in the head portion of the body.
- 81. (New) Apparatus according to claim 78, wherein:
 the body comprises a proximal head portion having a proximal
 end, the proximal head portion defining at least one hole
 therethrough, and the proximal head portion defining a
 longitudinal channel open to the at least one hole and to the
 proximal end; and

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the retrieving device comprises a bendable, resilient elongated element, which includes a forward end, the elongated element being adapted to be inserted into the at least one hole and through at least a portion of the channel, and through the proximal end of the proximal head portion, and then through the bone, to thereby indicate a location on the external surface of the bone substantially directly over the proximal end of the proximal head portion.

82. (New) Apparatus according to claim 81, wherein said forward end of said elongated element includes a sharp tip.